510(k) Summary

Submitter

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DEC 2 1 2006

Contact Person

James Jenkins
Regulatory Associate
952-653-2412

Date Prepared

December 14, 2006

Trade Name

Enpath Medical ViaSeal Valved Peelable Introducer

Common Name

Catheter Introducer

Classification Name

Catheter Introducer (21 CFR 870.1340, Product Code DYB)

Predicate Device

Enpath Medical FlowGuard Valved Peelable Introducer; K040150.
Thomas Medical Products Inc., SafeSheath MSP Introducer Kit with Integral Hemostasis Valve; K003731

Device Description

The Enpath ViaSeal Valved Peelable Introducer is a small diameter tubular shaped device with integrated proximal handles. The ViaSeal Valved Peelable Introducer is designed to provide a relatively atraumatic method for implanting catheters and pacemaker leads into the venous system while providing hemostatic sealing to venous pressures. The ViaSeal Valved Peelable Introducer has a "peel-away" feature common to the predicate device. This feature allows the user to remove the introducer without removing the inserted catheter or pacing lead.

The ViaSeal Valved Peelable Introducer is packaged in a sterile 5-pack convenience kit containing a ViaSeal Valved Peelable Introducer, a thin-wall

needle, a disposable syringe, and a flexible guidewire. The kit is packaged in a PETG tray with a Tyvek lid, and a sealed Tyvek/LDPE pouch.

Introducer sizes of the sheath and dilator range from 7 French to 10.5 French. The materials and construction are the same for all French sizes. Enpath ViaSeal Valved Peelable Introducer kits will be packaged and ETO sterilized for one time use and sealed in a Tyvek/LDPE pouch.

Intended Use

The Enpath ViaSeal Valved Peelable Introducer is intended for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Comparison of Technological Characteristics

All technological characteristics of the Enpath ViaSeal Valved Peelable Introducer are substantially equivalent to the predicate device; FlowGuard Valved Peelable Introducer (K040150) including indications for use, operation, manufacturing process, biocompatibility, sterilization method, and packaging. The Enpath ViaSeal Valved Peelable Introducer is also substantially equivalent to the Thomas Medical Products Inc. SafeSheath Introducer Kit with Integral Hemostasis Valve, K003731, with respect to indications for use, sterilization method, materials, packaging, hemostatic sealing to venous pressures, French sizes, and available lengths (13 and 25 cm).

Summary of Studies

The performance testing for this device included testing to verify that the device functions in a safe and effective manner. The performance testing included the device specifications, dimensional and functional testing, and hemostatsis of the device to venous pressures. Test results verify that the device performs per specification requirements and is equivalent to the predicate device without creating additional risk to the patient or user.
No clinical evaluations for this submission have been conducted.

Substantial Equivalence

The ViaSeal Valved Peelable Introducer is as safe, as effective, and performs as well as, and is substantially equivalent to the original "cleared" FlowGuard Valved Peelable Introducer, K040150. The ViaSeal Valved Peelable Introducer is also substantially equivalent to the Thomas Medical Products Inc. SafeSheath Introducer Kit with Integral Hemostasis Valve (K003731) with respect to intended use (the introduction of various pacing leads and catheters), device classification (Class II, 21 CFR 870.1340), product code (DYB), and hemostatic sealing to venous pressures.

(Note: This document uses the term "substantial equivalence" as intended in 21 CFR 807.88, and not as defined in Title 35 of the U.S. Code.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2006

Enpath Medical Inc.
James Jenkins, Regulatory Associate
15301 Highway 55 West
Minneapolis MN 55447

Re: K063182
Trade/Device Name: Enpath Medical ViaSeal Valved Peelable Introducer
Regulation Number: 21 CFR Sec. 870.1340
Regulation Name: Catheter, Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 14, 2006
Received: December 15, 2006

Dear Mr. Jenkins

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

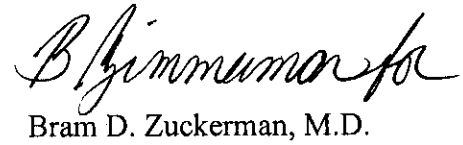
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use

510(k) Number (if known): K063182

Device Name: ViaSeal Valved Peelable Introducer

Indications for Use: The Enpath ViaSeal Valved Peelable Introducer is indicated for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K063182

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number